

# PSJ3

## Exhibit 463

**From:** Dempsey, Michele [GPSUS]  
**To:** Kohn, Robyn [JAN]  
**CC:** Quinn, Margaret [MCCUS]  
**Sent:** 8/31/2011 3:58:46 PM  
**Subject:** RE: DEA - Hydrocodone

Thank you Robyn for this information. Please keep me in the loop in the future.

Regards,  
Michele

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**From:** Kohn, Robyn [JAN]  
**Sent:** Tuesday, August 30, 2011 6:51 PM  
**To:** Quinn, Margaret [MCCUS]; Chupa, Kati [GSMMMAUS]  
**Cc:** Dempsey, Michele [GPSUS]  
**Subject:** RE: DEA - Hydrocodone

Thanks Margaret and Michele for further detail and partnership.

Kati, our advocacy partners including our Pain Care Forum partners continue to monitor and openly address the half dozen bills introduced around these issues. I attached the summary of the Buchanan Bill (H.R. 1065, the Pill Mill Crackdown Act by Rep. Buchanan) which may be helpful; up-scheduling of hydrocodone is part of this Fed. Bill.

Here is a short list of other recent legislative actions that are monitored along with our pain partners:

- H.R. 1266, the Fraudulent Prescription Prevention Act by Rep. Grimm
- H.R. 1316, the Stop Oxy Abuse Act by Rep. Bono Mack
- H.R. 2119, the Ryan Creedon Act by Rep. Bono Mack
- S. 507, the Prescription Drug Abuse Prevention and Treatment Act by Sen. Rockefeller
- S. 882, the STOP Act by Sen. Brown (OH)

We will keep all informed. Please advise us of questions/comments. Best regards, Robyn

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**From:** Quinn, Margaret [MCCUS]  
**Sent:** Monday, August 29, 2011 3:50 PM  
**To:** Chupa, Kati [GSMMMAUS]; Kohn, Robyn [JAN]  
**Cc:** Dempsey, Michele [GPSUS]  
**Subject:** FW: DEA - Hydrocodone

Robyn and Kati:

Michele Dempsey, Director of DEA Compliance at Noramco provided the following additional information.

I hope this is helpful. Let me know if we can be of any additional assistance. m

Thank you Michele!

Margaret Quinn  
Corporate Government Affairs and Policy

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**From:** Dempsey, Michele [GPSUS]  
**Sent:** Monday, August 22, 2011 9:50 PM  
**To:** Sheroff, Robert [JSGUS]  
**Cc:** Chilson, Scott [JSGUS]; Billington, Courtney [JSGUS]; De Keersmaecker, Filip [JNJCH]  
**Subject:** RE: DEA - Hydrocodone

Hi Bob -  
I saw this article was in the Delaware News Journal yesterday.

There are 2 ways to change the schedule of a drug. One is administratively – DEA and FDA agree to reschedule. All in the Industry knows FDA won't budge on the suggestion of moving HBT products from Sch III to Sch II. DEA has been complaining many years now. The other way is legislatively which is what Congress is doing in the House Bill (section 7 of the attached): <http://www.govtrack.us/congress/billtext.xpd?bill=h112-1065>

Dihydrocodeinone is another name for hydrocodone.

Mark Caverly, head of policy and liaison at DEA until this past March when he retired told me the House Bill takes statutory language currently in the Controlled Substance Act and proposes to remove or revoke it. It appears to address the long-standing exemption from CII of the combination hydrocodone products. Most bills are not enacted so this may never see the light of day.

But if this bill does make it - this will reshape the Noramco business. Noramco holds 45% of the hydrocodone aggregate quota. The change in schedule could have an impact on demand from Watson and Vintage (our largest customer). As the article says, doctors don't like to prescribe Sch II. WWNF is keeping an eye on this. Bill Grubb has already reached out to Government Affairs for their incite.

Tapentadol – this will be great news for Nucynta. It puts us all on the same playing field.

And lastly, it has little impact on our dealing with Washington. Noramco API is far down the hydrocodone supply chain and we are a company in good standing. Our data shows no apparent abuse of Nucynta. So far so good!

Let me know if you have any other questions.

Regards,  
Michele

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**From:** Sheroff, Robert [JSGUS]  
**Sent:** Monday, August 22, 2011 7:27 AM  
**To:** Dempsey, Michele [GPSUS]  
**Cc:** Chilson, Scott [JSGUS]; Billington, Courtney [JSGUS]; De Keersmaecker, Filip [JNJCH]  
**Subject:** DEA - Hydrocodone

Michele,  
FYI - This may have some impact on our dealings with DEA.  
Bob

**Abuse of Narcotic Hydrocodone on the Rise**

Health agencies and drug counselors are warning of a dramatic and dangerous rise in the abuse of medicines containing the narcotic hydrocodone, including Vicodin, Norco and Lortab. In March, alarmed by the rising rates of abuse, 58 members of Congress filed a bill that would bypass the DEA and FDA's rulemaking process and tighten controls on hydrocodone. Legitimate pain patients, meanwhile, are worried that such a move could jack up their medical expenses by forcing them to repeatedly return to their doctors for refills. ASSOCIATED PRESS

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